Statement

PhRMA

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PhRMA Responses to
CDER Questions for
CDER Stakeholders Meeting

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Good Morning,

I am Dr. Bert Spilker, Senior Vice President of the Pharmaceutical Research and Manufacturers of America. My comments this morning must of necessity be condensed in order to fit the allotted time. Further details and substantiation will be submitted to the Docket.

PhRMA appreciates the opportunity to provide input as FDA considers how best to achieve compliance with the Agency's various statutory obligations. It is important to underscore, however, that consultation with stakeholders like PhRMA does not relieve FDA from the ultimate responsibility to manage and, as necessary, re-allocate its resources to achieve the statutory timelines and other goals of the FD&C Act in a timely manner.

Q.I on Drug Marketing and Advertising

We wish to make three points.

1. We applaud FDA's new policy on Direct-to-Consumer Advertising. We believe Direct-to-Consumer Ads serves the public health interest, particularly with an increased movement to self-care management:

   - these ads empower patients with information about health conditions and treatment options,
   - they prompt patients to seek medical help,
   - they promote informed discussion between physicians and patients; and
   - they promote treatment of underserved populations.

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We look forward to working closely with the FDA as you evaluate the guidelines; meanwhile, industry takes seriously the responsibility of reaching patients with this information, and acts in good faith to follow FDA's already precise and thorough guidelines.

2. A recent comprehensive DTC survey by Prevention magazine has clearly demonstrated that

   - ♦DTC information promotes public health by prompting physician-patient dialogue
   - ♦DTC is particularly valuable in prompting patients to seek physician advice about previously undiagnosed medical conditions
   - ♦DTC information also improves compliance by patients with their physician's advice about Rx drugs

3. The question FDA posed: "How can we better assure that drug advertisements communicate appropriate messages?" overstates the responsibility and authority of the FDA.

Q. II on Inspections

In regard to FDA's inspectional programs for pharmaceutical Good Manufacturing Practice compliance (GMP), PhRMA believes that CDER should take a more comprehensive approach in the management and coordination of this activity. Our members see a need to involve all of the different parts of the Agency along with the regulated industry in a collaborative effort aimed at assuring an effective and efficient program.

We have 8 specific points to make that will be discussed in the response to the Docket.

The following specific issues have been identified by PhRMA members:

1. The current inspection program is generally adequate in terms of pre-approval inspections conducted to meet PDUFA milestones.

2. Although we recognize that FDA has made improvements, our members continue to see incidents where the field investigator is second-guessing the already approved drug specifications within an application.

3. PhRMA notes that other FDA-regulated facilities are subject to scheduled or preannounced GMP inspections. We would like to see a pilot program applicable to pharmaceutical facilities instituted using that approach.

4. In the conduct of pharmaceutical GMP inspections, FDA should focus on critical system deficiencies rather than enumerating a long list of trivial citation/details, many of which are easily and immediately corrected.

5. Although intended to reward firms with good performance, we are skeptical about the FDA's "first party" audit pilot program of self-inspection because:

    1. Participating companies would be expected to share internal audit data.
    2. We do not see any benefit to the industry or companies from this program as proposed.
    3. The approach did not involve industry at all in designing the program. We are ready to help the Agency design a program with practical benefits for both participating firms and the agency.

6. GAO's report on foreign inspections, conducted at the request of Congressman Barton, raised numerous management issues that should be addressed. These include revising FDA's foreign inspection strategy to provide assurance that all foreign manufacturers exporting approved products to the U.S. comply with U.S. standards.

7. Given the increasing number of bulk products and finished drugs being made outside the U.S., increasing reliance on partnerships such as the MRA offer a way to help achieve the Agency's mission in a cost effective way.

8. PhRMA believes that the duration of inspections in the U.S. is excessive compared with inspectional coverage at overseas locations.

Q. III on Drug Information

There is a need for health care providers to have access to the latest scientific information on medicines.

1. Dissemination of information is distinct from promotion (For example, see the text and legislative history of FDAMA section 401, and PhRMA comments submitted to the rulemaking docket). Information on off-label use (e.g., peer-reviewed scientific journal articles) is appropriately provided to health care professionals by research pharmaceutical manufacturers, who are perhaps the most knowledgeable about such information. FDA must assure that any regulatory limitations on the flow of such

information is (a) as minimally intrusive as possible, (b) consistent with both constitutionally-guaranteed speech rights and (c) FDAMA.

2. Electronic package inserts are a positive means of spreading information to consumers and health care professionals.

Q. IV on Surveillance and Adverse Event Reporting

We wish to make five points:

1. There is nothing more important to the pharmaceutical industry than the safety of our products. Every day, worldwide, our companies are monitoring the safety of their products. We have extensive systems in place today to collect safety data and we report to the FDA all adverse reactions according to regulations.

2. The FDA should stress to Congress, the press and the public that the current safety standards for new drug approval are significantly higher than in the past. For example, in 1980 there were an average of 1500 patients studied in 34 clinical trials in the average NDA. These numbers have risen to over 4,000 patients in 68 clinical trials. The amount of safety data is related to the number of patients exposed to a new drug.

3. We support the views of 21 patient organizations, who wrote to USA Today last week to emphasize that

   - "the FDA has not comprised its world-class standards for the safety and effectiveness of new medicines" and

   - They "fear that in overreaction to a small number of recent drug withdrawals, policy makers may decide to slow down the drug approval process. This would hurt public health and harm the patients we represent by denying them the new treatments and cures they are so anxious to receive."

4. Both FDA and the pharmaceutical industry must educate Congress, the press and the public about the vast amount of safety activities already in place. Recent drug withdrawals demonstrate that the systems are basically working - not that they are broken.

5. To the extent that the system for monitoring the safety of medicines after they are on the market can be improved, the pharmaceutical industry is eager to work with the FDA, patients, doctors, pharmacists, hospitals, Congress, and anyone else to achieve that goal.

Q. V on Balance will be addressed in comments to the Docket.

Q. VI is on Priorities

More interaction and collaboration is highly desirable between FDA and the regulated industries to avoid issuing guidances that do not adequately take into account useful perspectives that can be provided by industry.

The agency rarely says "here's an issue – what do you think about it and how should we proceed?" A positive model was that used by the FDA for pregnancy labeling. An unproductive model was the guidance on gender, because it was issued as a final rule without industry input.

Thank you for the opportunity of addressing you this morning.